Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

WHO International Standard
Alpha-Fetoprotein, human (2nd WHO International Standard)
NIBSC code: 22/216
Instructions for use
(Version 1.0, Dated 10/11/2023)

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1. INTENDED USE

The WHO International Standard for Alpha-Fetoprotein (AFP) is intended for the calibration and monitoring of AFP immunoassays. This preparation, coded 22/216, serves as a replacement to the 1st WHO IS, 72/225 which was first established in 1975 and is now exhausted (1,2,3).

22/216 was evaluated via an international collaborative study and assigned a potency in International Units (IU). However, many immunoassays report in nanograms (ng). Therefore, a pre-existing conversion factor where 1 IU approximately equals 1.21 (1.02-1.43) ng of AFP was used during value assignment (4,5).

2. CAUTION

This preparation is not for administration to humans or animals in the human food chain.

The preparation contains material of human origin, and either the final product or the source materials, from which it is derived, have been tested and found negative for HBsAg, anti-HIV and HCV RNA. As with all materials of biological origin, this preparation should be regarded as potentially hazardous to health. It should be used and discarded according to your own laboratory's safety procedures. Such safety procedures should include the wearing of protective gloves and avoiding the generation of aerosols. Care should be exercised in opening ampoules or vials, to avoid cuts.

3. UNITAGE

7800 International Units (IU) per ampoule

4. CONTENTS

Country of origin of biological material: United States.
Each ampoule contains residue after freeze-drying 1.0 mL of solution that contained:

Approx 12 µg Alpha-Fetoprotein (purified, human cord serum) diluted in normal human serum

5. STORAGE

Unopened ampoules should be stored at -20°C
Please note because of the inherent stability of lyophilized material, NIBSC may ship these materials at ambient temperature.

6. DIRECTIONS FOR OPENING

DIN ampoules have an 'easy-open' coloured stress point, where the narrow ampoule stem joins the wider ampoule body. Various types of ampoule breaker are available commercially. To open the ampoule, tap the ampoule gently to collect material at the bottom (labelled) end and follow manufactures instructions provided with the ampoule breaker.

7. USE OF MATERIAL

No attempt should be made to weigh out any portion of the freeze-dried material prior to reconstitution
For practical purposes each ampoule contains the same quantity of Alpha-Fetoprotein. The entire content of each ampoule should be completely dissolved in an accurately measured amount of buffer solution. The use of water to reconstitute ampoule contents is not recommended. The material has not been sterilized and the ampoules contain no bacteriostat.

8. STABILITY

Reference materials are held at NIBSC within assured, temperature-controlled storage facilities. Reference Materials should be stored on receipt as indicated on the label.

NIBSC follows the policy of WHO with respect to its reference materials.

9. REFERENCES

1. K Partridge, M Moore, E Atkinson, P Rigsby and B Cowper. WHO 2nd International Standard Alpha-Fetoprotein. WHO/BS/2023.2461
2. WHO Technical Report Series No.594,1976,14
3. Sizaret P, Anderson S G, The International Reference Preparation for alphafoetoprotein. J of Biol. Stand., 4, 149, 1976
4.Sizaret P et al, Equivalence between international units and mass units of alphafoetoprotein. Report of a collaborative study. Clinica Chimica Acta, 96, 59-65, 1979
5. Sizaret P, Breslow N, Anderson S G, and 12 other participants, Collaborative study of a preparation of human cord serum for its use as a reference in the assay of alphafoetoprotein, J Biol. Stand 3, 201-223, 1975

10. ACKNOWLEDGEMENTS

We gratefully acknowledge the important contributions of all participants in the collaborative study, Dr Cathie Sturgeon of NEQAS, who kindly helped test the bulk material, and the Standardisation Science Group and Standards Processing Divison at NIBSC for the preparation and dispatch of ampouled materials.t

11. FURTHER INFORMATION

Further information can be obtained as follows;
This material: enquiries@nibsc.org
WHO Biological Standards:
http://www.who.int/biologicals/en/
JCTLM Higher order reference materials:
http://www.bipm.org/en/committees/jc/jctlm/
Derivation of International Units:
http://www.nibsc.org/standardisation/international_standards.aspx
Ordering standards from NIBSC:
http://www.nibsc.org/products/ordering.aspx
NIBSC Terms & Conditions:
http://www.nibsc.org/terms_and_conditions.aspx

12. CUSTOMER FEEDBACK

Customers are encouraged to provide feedback on the suitability or use of the material provided or other aspects of our service. Please send any comments to enquiries@nibsc.org

13. CITATION

In all publications, including data sheets, in which this material is referenced, it is important that the preparation's title, its status, the NIBSC code number, and the name and address of NIBSC are cited and cited correctly.

14. MATERIAL SAFETY SHEET

Classification in accordance with Directive 2000/54/EC, Regulation (EC) No 1272/2008: Not applicable or not classified

National Institute for Biological Standards and Control,
Potters Bar, Hertfordshire, EN6 3QG. T +44 (0)1707 641000, nibsc.org
WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory

World Health Organization

Physical and Chemical properties			
Physical appearance: Yellow-ish freeze dried powder		Corrosive:	No
Stable:	Yes	Oxidising:	No
Hygroscopic:	Yes	Irritant:	No
Flammable:	No	Handling: See caution, Section 2	
Other (specify):	Contains material of human origin.		

Toxicological properties	
Effects of inhalation:	Not established, avoid inhalation
Effects of ingestion:	Not established, avoid ingestion
Effects of skin absorption:	Not established, avoid contact with skin

Suggested First Aid	
Inhalation:	Seek medical advice
Ingestion:	Seek medical advice
Contact with eyes:	Wash with copious amounts of water. Seek medical advice
Contact with skin:	Wash thoroughly with water.

Action on Spillage and Method of Disposal
Spillage of ampoule contents should be taken up with absorbent material wetted with an appropriate disinfectant. Rinse area with an appropriate disinfectant followed by water. Absorbent materials used to treat spillage should be treated as biological waste.

15. LIABILITY AND LOSS

In the event that this document is translated into another language, the English language version shall prevail in the event of any inconsistencies between the documents.
Unless expressly stated otherwise by NIBSC, NIBSC's Standard Terms and Conditions for the Supply of Materials (available at http://www.nibsc.org/About_Us/Terms_and_Conditions.aspx or upon request by the Recipient) ("Conditions") apply to the exclusion of all other terms and are hereby incorporated into this document by reference. The Recipient's attention is drawn in particular to the provisions of clause 11 of the Conditions.

16. INFORMATION FOR CUSTOMS USE ONLY

Country of origin for customs purposes*: United Kingdom * Defined as the country where the goods have been produced and/or sufficiently processed to be classed as originating from the country of supply, for example a change of state such as freeze-drying.
Net weight: 89.2 mg
Toxicity Statement: Toxicity not assessed
Veterinary certificate or other statement if applicable. **Attached:** No

17. CERTIFICATE OF ANALYSIS

NIBSC does not provide a Certificate of Analysis for WHO Biological Reference Materials because they are internationally recognised primary reference materials fully described in the instructions for use. The reference materials are established according to the WHO Recommendations for the preparation, characterization and establishment of international and other biological reference standards http://www.who.int/bloodproducts/publications/TRS932Annex2_Inter_biolefstandardsrev2004.pdf (revised 2004). They are officially endorsed by the WHO Expert Committee on Biological Standardization (ECBS) based on the report of the international collaborative study which established their suitability for the intended use.